

**IN THE CLAIMS:**

Please amend the claims as follows:

1. (Currently Amended) A dispersible or orodispersible solid pharmaceutical composition comprising:

particles having a size lower than 710  $\mu\text{m}$  upon dispersion into water, containing a metformin active ingredient, wherein the particles comprise:

a) from 65% to 90% by weight of the metformin active ingredient, optionally provided in the form of a salt, or a combination of the metformin active ingredient with a hypoglycemic active ingredient;

b) from 0.5 to 4% by weight of a binding agent or a combination of binding agents;

c) from 1% to 12% by weight of a disintegrating agent or a combination of disintegrating agents;

d) from 0% to 10% by weight of a diluting agent or a combination of diluting agents;

e) from 0.05% to 3% by weight of a sweetening agent or a combination of sweetening agents; and

f) one or more additional excipients,

the weight percentages being expressed based on the total weight of said composition.

2. (Previously Presented) A composition according to claim 1, further comprising from 0.01% to 6% by weight of a flavouring agent, or a combination of flavouring agents.
3. (Previously Presented) A composition according to claim 1, wherein the binding agent(s) are selected from the group consisting of polyvinylpyrrolidone, sodium carboxymethylcellulose, alginic acid, hydroxypropylmethylcellulose and polyethylene oxide.
4. (Previously Presented) A composition according to claim 1, wherein the disintegrating agent(s) are selected from the group consisting of sodium croscarmellose, cross-linked polyvinylpyrrolidone, sodium starch glycolate, wheat or corn starch and pre-gelatinized starch.
5. (Previously Presented) A composition according to claim 1, wherein the diluting agent(s) are selected from the group consisting of lactose, mannitol, cellulose, microcrystalline cellulose and calcium carbonate.
6. (Previously Presented) A composition according to claim 1, wherein the sweetening agent(s) are selected from the group consisting of gluconate, aspartame, cyclamate, sodium saccharinate, xylitol and maltitol.

7. (Previously Presented) A composition according to claim 2, wherein the flavouring agent(s) are selected from the group consisting of fruit flavour, mint flavour, anise flavour, honey flavour, vanilla flavour, tea flavour, and verbena flavour.

8. (Currently Amended) A composition according to claim 1, wherein the metformin active ingredient is provided in the form of a hydrochloride salt selected from the group consisting of the phosphate, sulfate, hydrochloride, salicylate, maleate, benzoate, ethanedisulfonate, fumarate, succinate, chlorophenoxyacetate, embonate and glycolate salts.

9. (Previously Presented) A composition according to claim 1, wherein the hypoglycemic active ingredient, when present, is selected from the group consisting of glicazide, glipizide, chlorpropamid, glimepiride, glibenclamide, and combinations thereof.

10. (Previously Presented) A composition according to claim 1 further comprising a PPAR Gamma agonist (peroxisome proliferator-activated receptor gamma) selected from the group consisting of rosiglitazone, pioglitazone, and balaglitazone and combinations thereof.

11. (Previously Presented) A composition according to claim 1 further comprising a PPAR Gamma and Alpha agonist selected from the group consisting of terapglitazar, muraglitazar, and ragaglitazar and combinations thereof.

12. (Cancelled)

13. (Previously Presented) A composition according to claim 1 further comprising a dipeptidyl peptidase inhibitor (DPPIV).

14. (Previously Presented) A composition according to claim 1 further comprising acarbose.

15. (Previously Presented) A composition according to claim 1, comprising:

a) from 65% to 80% by weight of the metformin active ingredient, optionally provided in the form of a salt, or a combination of the metformin active ingredient with a hypoglycemic active ingredient;

b) from 0.5 to 4% by weight of a water-soluble polyvinylpyrrolidone with a molecular ranging from 44,000 to 54,000;

c) from 1% to 10% by weight of a water-insoluble cross-linked polyvinylpyrrolidone;

d) from 0.5% to 10% by weight of a diluting agent or a combination of diluting agents;

e) from 0.05% to 3% by weight of a sweetening agent or a combination of sweetening agents; and

f) one or more additional excipients,

the weight percentages being expressed based on the total weight of said composition.

16. (Previously Presented) A composition according to claim 1, wherein the particles comprise (i) an internal core comprising the active ingredient or the combination of active ingredients, in association with one or more excipients and (ii) an external layer comprising the sweetening agent.

17. (Previously Presented) A composition according to claim 16, wherein the internal core accounts for 75% to 85% by weight and the external layer accounts for 15% to 25% by weight, based on the total weight of the composition.

18. (Previously Presented) A composition according to any one of claims 16 or 17, wherein:

(i) the internal core comprises:

a) from 65% to 80% by weight of the metformin active ingredient, optionally provided in the form of a salt or a combination of the metformin active ingredient with a hypoglycemic active ingredient, and

b) from 0.5% to 4% by weight of a binding agent or a combination of binding agents;

and

(ii) the external layer is non-film coated and comprises:



a) from 0% to 10% by weight of a diluting agent or a combination of diluting agents;

b) from 1% to 10% by weight of a disintegrating agent or a combination of disintegrating agents; and

c) from 0.05% to 3% by weight of a sweetening agent or a combination of sweetening agents;

the weight percentages being expressed based on the total weight of said composition.

19. (Previously Presented) A composition according to claim 18, wherein the binding agent is a water-soluble polyvinylpyrrolidone with a molecular weight ranging from 44,000 to 54,000.

20. (Previously Presented) A composition according to claim 18, wherein the disintegrating agent is a water-insoluble cross-linked polyvinylpyrrolidone.

21. (Previously Presented) A composition according to claim 18, wherein:

(i) the internal core comprises:

a) from 76% to 77% by weight of the metformin active ingredient, optionally provided in the form of a salt or a combination of the metformin active ingredient with a hypoglycemic active ingredient, and

b) from 2.5% to 3.5% by weight of a water-soluble polyvinylpyrrolidone with a molecular weight ranging from 44,000 to 54,000;

and

(ii) the external non film-coated layer comprises:

a) from 6.5% to 7.5% by weight of a diluting agent or a combination of diluting agents;

b) from 4.5% to 5.5% by weight of a water-insoluble cross-linked polyvinylpyrrolidone; and

c) from 0.5% to 2.5% by weight of a sweetening agent or a combination of sweetening agents;

the weight percentages being expressed based on the total weight of said composition.

22. (Previously Presented) A composition according to claim 1, wherein the particles comprise:

(i) an internal core comprising:

a) 76.92% by weight of the metformin hydrochloride active ingredient, and

b) 3.08% by weight of a water-soluble polyvinylpyrrolidone with a molecular weight ranging from 44,000 to 54,000;

and

(ii) an external non film-coated layer comprising:

a) 7% by weight of a diluting agent or of a combination of diluting agents;

b) 5% by weight of a water-insoluble cross-linked polyvinylpyrrolidone;

c) 2% by weight of a sweetening agent or a combination of sweetening agents;

d) 5% by weight of a flavouring agent or a combination of flavouring agents; and

e) 1% by weight of a preservative;

the weight percentages being expressed based on the total weight of said composition.

23. (Previously Presented) A hydrodispersible non film-coated pharmaceutical tablet, comprising a composition according to claim 1.

24. (Previously Presented) A tablet according to claim 23, wherein a pharmacokinetic profile is established from two tablets, each dosed at 500 mg, which is characterized by an area under the plasma concentration curve measured *in vivo* (AUC) ranging from 10000 ng.h/ml to 16250 ng.h/ml.

25. (Previously Presented) A tablet according to claim 23 or 24, wherein a pharmacokinetic profile is established from two tablets, each dosed at 500 mg, which is characterized by a maximum plasma concentration value ( $C_{max}$ ) ranging from 1600 ng/ml to 2600 ng/ml.

26. (Previously Presented) A tablet according to claim 23 or 24, wherein a pharmacokinetic profile is established from two tablets, each dosed at 500 mg, which is characterized by a  $T_{max}$  value ranging from 2h and 3.25h.

27. (Cancelled)



28. (Previously Presented) A tablet according to claim 23, wherein the tablet comprises 500 mg of metformin hydrochloride, and releases between 50% and 100% of the metformin hydrochloride dose in 5 minutes in a physiological buffer medium at pH 6.8 at 37°C.

29. (Currently Amended) A method for preparing a hydrodispersible non film-coated pharmaceutical tablet, comprising:

a) preparing an internal core comprising a dispersible or orodispersible solid pharmaceutical composition having the form of particles with a size lower than 710  $\mu\text{m}$  upon dispersion into water, containing a metformin active ingredient, the particles comprising:

1) from 65% to 90% by weight of the metformin active ingredient, optionally provided in the form of a salt, or a combination of the metformin active ingredient with a hypoglycemic active ingredient;

2) from 0.5 to 4% by weight of a binding agent or a combination of binding agents;

3) from 1% to 12% by weight of a disintegrating agent or a combination of disintegrating agents;

4) from 0% to 10% by weight of a diluting agent or a combination of diluting agents; and

5) one or more additional excipients,

through wet granulation of a mixture of metformin active ingredient, optionally provided in the form of a salt, and a binding agent, or a combination of metformin active ingredient with a hypoglycemic active ingredient, and a binding agent;

b) drying the particles obtained in step a);

c) adding to the particles obtained in step b) a mixture of excipients forming an external layer comprising from 0.05% to 3% by weight of a sweetening agent or a combination of sweetening agents; the weight percentages being expressed based on the total weight of said composition; and

d) performing a compression of the particles obtained in step c).

30. (Currently Amended) A method for preparing a hydrodispersible non film-coated pharmaceutical tablet, comprising:

a) preparing an internal core comprising a dispersible or orodispersible solid pharmaceutical composition having the form of particles with a size lower than 710  $\mu\text{m}$  upon dispersion into water, containing a metformin active ingredient, the particles comprising:

1) from 65% to 90% by weight of the metformin active ingredient, optionally provided in the form of a salt, or a combination of the metformin active ingredient with a hypoglycemic active ingredient;

2) from 0.5 to 4% by weight of a binding agent or a combination of binding agents;

3) from 1% to 12% by weight of a disintegrating agent or a combination of disintegrating agents;

4) from 0% to 10% by weight of a diluting agent or a combination of diluting agents; and

5) one or more additional excipients,

through dry granulation of a mixture of metformin active ingredient, optionally provided in the form of a salt, and a binding agent, or a combination of metformin active ingredient with a hypoglycemic active ingredient, and a binding agent;

b) compacting the dry particles obtained in step a);

c) adding to the particles obtained in step b) a mixture of excipients forming an external layer comprising from 0.05% to 3% by weight of a sweetening agent or a combination of sweetening agents; the weight percentages being expressed based on the total weight of said composition; and

d) performing a compression of the particles obtained in step c).

31. (Currently Amended) A method for preparing a hydrodispersible non film-coated pharmaceutical tablet, comprising:

a) preparing a mixture of (i) an internal core comprising a dispersible or orodispersible solid pharmaceutical composition having the form of particles with a size lower than 710  $\mu\text{m}$  upon dispersion into water, containing a metformin active ingredient, the particles comprising:

1) from 65% to 90% by weight of the metformin active ingredient, optionally provided in the form of a salt, or a combination of the metformin active ingredient with a hypoglycemic active ingredient;

2) from 0.5 to 4% by weight of a binding agent or a combination of binding agents;

3) from 1% to 12% by weight of a disintegrating agent or a combination of disintegrating agents;

4) from 0% to 10% by weight of a diluting agent or a combination of diluting agents; and

5) one or more additional excipients,

through dry granulation of a mixture of metformin active ingredient, optionally provided in the form of a salt, and a binding agent, or a combination of metformin active ingredient with a hypoglycaemic active ingredient, and the binding agent;

b) adding to the particles obtained in step a) a mixture of excipients forming an external layer comprising from 0.05% to 3% by weight of a sweetening agent or a combination of sweetening agents; the weight percentages being expressed based on the total weight of said composition; and

c) performing a compression of the particles obtained in step b).